IOM versus no IOM during surgical resection of contrast enhancing motor eloquent tumors – two comparable prospective observational cohorts

Protocol version 1

(01.11.2021)

Type of study: prospective observational cohort study

Hypothesis: That the use of IOM is associated with a higher extent of tumor resection and better neurological outcome at day 1 and day 30 post-surgery.

Primary outcomes:

- Extent of tumor resection evaluated on MRI scan the first post-op day
- Neurological outcome (day 1 and day 30 – specific tests, see below)

Secondary outcomes:

- Death at 30 days, 3 months and 6 months post-surgery
- Tumor progression at 3 months and 6 months
- Performance status, Karnofsky score, Modified Rankin Scale, GCS and NIHSS at day 1 and day 30.
- Complications at 30 days (lung emboly, deep venous thrombosis, cerebral infarction etc)

Statistical design: superiority

Funding: none

Decleration of interests: We declare no competing interests

Study inclusion criteria

- ✓ Indication for resection of contrast enhancing lesion in MRI (HGG/GBM, MET)
- ✓ Intention to reach either GTR or CRET
- ✓ No recurrent surgery
- ✓ Motor eloquence defined as closer than 20mm to either the CST (measured in preoperative DTI) or to the precentral gyrus
- ✓ Informed consent GCS 15 (or 14), elective or semi-elective surgery
- ✓ Pause of anticoagulant treatment according to local guidelines

Study exclusion criteria

- o Vulnerable persons such as pregnant woman or children
- o Patients being not able to sign informed consent
- o Emergency cases
- o Tumors involving both hemispheres

Data to be collected during the study

Baseline data
- Gender
- Age
- Comorbidity
- Medication
- Epileptic seizures before surgery
- Anti-epileptic drugs before surgery
- Tumor distance from eloquent area
- Tumor volumetry
- Tractography

Pre-op data/examination
- Left or right-handed.
- WHO performance status
- Karnofsky performance Scale
- Modified Rankin Scale
- GCS
- Muscle power assessment scale (MRC)
- NIHSS
- 9-hole peg test
- 10 meter walk test
- Gripstrength
- Six spot step test
- Engel classification

Surgical observations (neurosurgeon and anesthesia)
- IONM: yes or no
- Duration of surgery
- Resection stopped because of: IONM, fluroscein, neuronavigation, other
- Histology provided during surgery

- Sedation (type and duration)
- Other medication: hypertonic saline, mannitol

Peri-operative neurophys data
- TES MEP (present, irreversible significant alteration, loss)
- DCS MEP (present, irreversible significant alteration, loss)
- Lowest subcortical mapping threshold in mA

Post-op examination (1. Day after surgery)
- Early post-op MRC (extent of resection – volumetry. Significant ischemia?)
- WHO performance status
- Karnofsky performance Scale
- Modified Rankin Scale
- GCS
- Muscle power assessment scale (MRC)
- NIHSS
- 9-hole peg test
- 10 meter walk test
- Gripstrength
- Six spot step test
- Engel classification

Other post-op data
- Histology
- Epileptic seizures after surgery

Follow up (approx. 1-month post-surgery before start of oncologic treatment)
- NIHSS
- 9-hole peg test
- 10 meter walk test
- Gripstrength
- six spot step test

- Engel classification

- Number of AED

- WHO performance status

- Karnofsky performance Scale

- Modified Rankin Scale

- Muscle power assessment scale (MRC)

- Death

- Complications (lung emboly, deep venous thrombosis, cerebral infarction etc)

- Oncologic treatment (type of radiation, chemo etc)

Follow up 3 and 6 months (accordingly to follow-up MRIs)
- Progression-free survival
- Overall survival

On behalf of the research group

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